

IN THE CLAIMS

1. (original) A method for the sterilization of a labile glucocorticosteroid, comprising the step of applying a moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time.
2. (original) A method for the sterilization of a glucocorticosteroid, comprising the step of heating an aqueous suspension of a glucocorticosteroid, wherein the glucocorticosteroid has a sufficiently low solubility in water and is used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during heating.
3. (original) The method of claim 2, wherein at least 60% of the glucocorticosteroid is in the form of a suspension during heating.
4. (currently amended) The method of ~~any preceding claim 2~~, wherein said heating is at a temperature of from about 101°C to about 145°C.
5. (currently amended) The method of ~~any preceding claim 2~~, wherein said heating is carried out by autoclaving.
6. (currently amended) The method of ~~any preceding claim 2~~, wherein said heating is carried out for about 2 to about 180 minutes.
7. (currently amended) The method of ~~any preceding claim 2~~, wherein the suspension further comprises a surfactant.
8. (original) The method of claim 7, wherein the surfactant is present at a concentration of from about 0.75mg/ml to about 60mg/ml.
9. (currently amended) The method of ~~any preceding claim 2~~, wherein the glucocorticosteroid is budesonide or beclomethasone dipropionate.

10. (currently amended) The method of claim 9, wherein ~~the said~~ glucocorticosteroid is budesonide, and the heating is carried out at 121°C for about 20-30 minutes or at 110°C for about 120 minutes.

11. (currently amended) The method of claim 9, wherein ~~the said~~ glucocorticosteroid is beclomethasone dipropionate, and the heating carried out at 121°C for about 20-30 minutes or at 110°C for about 120 minutes.

12. (currently amended) The method of ~~any one of claims 2 to 11~~, wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml.

13. (original) A method for the sterilization of budesonide, comprising the step of heating an aqueous suspension of budesonide at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes.

14. (currently amended) The method of ~~any preceding claim 13~~, further comprising the step of diluting the suspension to a pharmaceutically suitable concentration.

15. (currently amended) A composition obtainable by [the method of] ~~any preceding claim~~ (i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml; (ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or (iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes.

16. (currently amended) A sterile aqueous suspension comprising a glucocorticosteroid obtained by [the method of] ~~of any of claims 1 to 14,~~ (i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml; (ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or (iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes, wherein the particle size of the glucocorticosteroid is such that the Dv100 is less than 20µm, the Dv90 is less than 10µm and the Dv50 is less than 5µm.

17. (currently amended) A sterile aqueous budesonide suspension obtained by [the method of] ~~of any of claims 1 to 14,~~ (i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml; (ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or (iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes, wherein the suspension comprises less than 0.2% by weight of 1,2-dihydro budesonide based on the amount of budesonide.